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Remarks

The Office Action mailed 24 March 2006 has been received and reviewed. Claims 34 and 34 having been amended, the pending claims are claims 34-84. Reconsideration and withdrawal of the rejections are respectfully requested.

Status of Claims

The Examiner asserted in the Office Action that "[c]laims 71-82 were withdrawn from consideration on the merits . . . as they are directed toward a non-elected invention." It is the applicants' position that claims 71-82 should not be considered as withdrawn, and should be examined. Thus, claims 45-66 and 70 are withdrawn, and claims 34-44, 67-69, and 71-84 are under examination.

Claims 71-82 were added with the Response to the Restriction Requirement, which was submitted August 16, 2004. Another Communication submitted to the Office on April 18, 2006, included four species elections. In the Office Action mailed July 28, 2005, the Examiner stated that "[b]ecause claims 70-82 are directed toward the non-elected species (these claims are drawn to wherein the immunogen comprises a siderophore receptor protein from a gram-positive bacterium; Applicant elected enterochelin, which is a siderophore from a gram-negative bacterium; i.e., e. coli or Salmonella) these claims are hereby withdrawn on the merits" (page 2 of the July 28, 2005 Office Action).

In the response submitted December 28, 2005, claims 71-82 were amended to change dependency from withdrawn independent claim 70 (which recites "wherein the immunogen comprises a siderophore receptor protein from a gram-positive bacterium") to examined independent claim 69 (which recites "wherein the immunogen comprises a siderophore receptor protein from a gram-negative bacterium"). The invention of claim 69 has been examined by the Examiner. Thus, claims 71-82 are directed to an elected invention.

The Examiner is respectfully requested to state on the record that claims 71-82 are directed to an elected invention, and examine the claims on the merits. In this regard it should be

noted that claims 71-82 recite subject matter similar to the examined claims 67-68 and 35-44, respectively.

Request for Corrected Filing Receipt

Applicants submitted a Request for Corrected Filing Receipt on 25 June 2004 and have not received a corrected filing receipt to this date. For the Examiner's convenience, Applicants have included a copy of the Request for Corrected Filing Receipt and the Filing Receipt with correction marked (marked Exhibits A and B, respectively) with date stamps from OIPE on 25 June 2004. These documents are also available in the Image File Wrapper on PAIR. Applicants respectfully request the Examiner's assistance in order to obtain a Corrected Filing Receipt.

Obviousness-Type Double Patenting Rejection

Claims 34-44 and 67-69 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 6,682,754. Upon an indication of otherwise allowable subject matter and in the event this rejection is maintained, Applicants will provide an appropriate response.

The 35 U.S.C. §112, First Paragraph, Rejection

The Examiner rejected claims 34-44, 83 and 84 under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, the Examiner alleged that the phrase "... wherein the implant provides for sustained release of the immunogen at least until the bird is capable of mounting an immune response" is not found in the Disclosure as originally filed, and is deemed to differ in scope from that which was originally disclosed. This rejection is respectfully traversed.

The Examiner has the initial burden of presenting by a preponderance of evidence why a skilled person would not recognize in an applicant's disclosure a description of the invention identified by the claims (M.P.E.P §2163.04). Whenever the issue of compliance with the Written Description requirement arises, the fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed (M.P.E.P §2163.02). "The subject matter of the claim need not be described literally (i.e., using the same terms or *in haec verba*) in order for the disclosure to satisfy the description requirement. If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application." M.P.E.P §2163.02. It is the applicants' position that claims 34 and 84 as examined are fully supported by the specification, and that inclusion of the phrase "at least" is not new matter. In the interests of furthering prosecution, claims 34 and 84 have been amended to delete "at least."

Reconsideration and withdrawal of this rejection is respectfully requested.

The 35 U.S.C. §103 Rejection

According to the Examiner, claims 34, 37, and 39-43 "remain rejected" and claims 67-69, 83, and 84 newly rejected under 35 U.S.C. §103(a) as being unpatentable over Emery et al. (U.S. Patent No. 5,830,479) in view of Phelps et al. (U.S. Patent No. 5,339,766) in view of Genovese et al. (Avian Pathology, 1998, Vol. 27(6), pg. 597). This rejection is respectfully traversed.

The statement that claims 34, 37, and 39-43 "remain rejected" is incorrect, as Genovese et al. has not been used in a former Office Action in this application to reject any claims. Accordingly, claims 34, 37, and 39-43 are *newly* rejected under Emery et al. in view of Phelps et al. in view of Genovese et al. Further, the Examiner did not repeat the 35 U.S.C. §103(a) rejection of claims 34, 37, and 39-43 over Emery et al. (U.S. Patent No. 5,830,479) in view of Phelps et al. (U.S. Patent No. 5,339,766), thus it is the applicants' understanding that the rejection

of claims 34, 37, and 39-43 over Emery et al. (U.S. Patent No. 5,830,479) in view of Phelps et al. (U.S. Patent No. 5,339,766) is withdrawn.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art references must teach or suggest all the claim limitations. *See* M.P.E.P. § 2143.

Applicants respectfully disagree that the Examiner has provided a *prima facie* case of obviousness, as Emery et al. in view of Phelps et al. in view of Genovese et al. does not teach or suggest all the claim limitations of claims 34, 37, 39-43, 67-69, 83, and 84. More specifically, Emery et al. in view of Phelps et al. in view of Genovese et al. does not provide "for sustained release of the immunogen at least until the bird is capable of mounting an immune response to the immunogen" (independent claims 34 and 84) or "for sustained release of the immunogen until a time when maternal antibodies of the bird to the immunogen are sufficiently reduced so that the bird is capable of mounting an immune response to the immunogen" (independent claim 69).

Emery et al. provides a vaccine composed of a substantially pure siderophore receptor protein that is useful for immunizing an avian or another animal against infection by gram-negative bacteria (see column 2, lines 13-27). Emery et al. further provides fourteen examples that describe the production and purification of siderophore receptor proteins, vaccination of turkey poults, and the ability of the siderophore receptor protein to provide cross-reactivity to varying immunogens.

Phelps et al., on the other hand, is not directed to the use of a novel immunogen, but rather provides "a method for injecting eggs to minimize the ingress of air and contaminants, and minimize the leakage of albumin from the egg." (column 3, lines 59-61). The method includes use of a sealant at the point of injection to prevent contamination and minimize leakage. While

this is a useful method of administering a variety of materials to an egg, and is in fact incorporated by reference in Applicants' specification, this reference does not teach or suggest providing sustained release of the immunogen at least until the bird is capable of mounting an immune response to the immunogen.

Genovese et al. presents experiments that evaluate the ability of Salmonella enteritidis-immune lymphokines derived from a virally transformed chicken T cell line in protecting day-old turkeys against Salmonella enteritidis liver invasion, inducing peripheral blood heterophilia, and functionally activating heterophiles when delivered by subcutaneous, oral, or intranasal routes when compared to intraperitoneal injection (see headnote, page 1 of the Genovese et al. document included with the Office Action). The Salmonella enteritidis-immune lymphokines delivered to the turkeys act "as an immunopotentiator during the first 7 days of life in poultry when . . . the immune response of these young birds is incompetent" (Genovese et al., page 5 of the Genovese et al. document included with the Office Action).

In the Office Action mailed July 28, 2005, the Examiner stated that "the ordinary artisan would have recognized that the most crucial time of vaccination delivery to a young bird is within the first few days of life." The response mailed December 28, 2005, noted that the Office was taking official notice of this and further noted that evidentiary support in the record was required. In the present Office Action, the Examiner continues to note that "the ordinary artisan would have recognized that the most crucial time of vaccination delivery to a young bird is within the first few days of life" (page 8 of the Office Action), and asserts Genovese et al. supports this assertion.

It is the applicants' position that Genovese et al. does not teach or suggest that "the most crucial time of vaccination delivery to a young bird is within the first few days of life." The Examiner is requested to note that Genovese et al. state vaccines can be used on newly hatched chicks and poults, but "maternal antibodies may cause interference with the vaccine and the desired immune response" (Genovese et al., page 5 of the Genovese et al. document included with the Office Action). Genovese et al. also states that "[o]ne to 7-day-old chicks and poults

have been shown to be immunologically incompetent" (Genovese et al. at page 2 of the Genovese et al. document included with the Office Action). Thus, delivery of vaccine to a young bird within the first few days of life is *not* recognized to be a crucial time for vaccination, as the effect of vaccination at this time is suppressed by the presence of the maternal antibodies, and the bird's immune system is incompetent. Likewise, the applicants have described the complications in vaccination that result from the presence of maternal antibodies, noting that "the presence of maternal antibodies can interfere with the ability of young birds to actively respond to an immunogen" (p. 1, lines 16-18 of the specification). Thus, it is respectfully maintained that the Examiner has not provided specific factual findings based on sound technical and scientific reasoning to support the assertion that "the ordinary artisan would have recognized that the most crucial time of vaccination delivery to a young bird is within the first few days of life." The Examiner is requested to provide documentary evidence that supports the assertion, or an affidavit or declaration setting forth specific factual statements and explanation to support the finding. M.P.E.P §2144.03(C).

The Examiner also notes that "it is deemed that the bird will elicit at least some immune response to the immunogen *in-ovo*" (Office Action at page 8, first full paragraph), but offers no support for such a statement. "Official notice unsupported by documentary evidence should only be taken by the examiner where the facts asserted to be well-known, or to be common knowledge in the art are capable of instant and unquestionable demonstration as being well-known." M.P.E.P §2144.03(A). The Office has not provided specific factual findings based on sound technical and scientific reasoning to support the assertion that a bird will elicit at least some immune response to an immunogen *in-ovo*. The Examiner is requested to provide documentary evidence that supports the assertion, or an affidavit or declaration setting forth specific factual statements and explanation to support the finding. M.P.E.P §2144.03(C).

The Examiner is requested to note that "[i]n the poultry industry, conventional vaccination programs are designed to be administered after the decline of maternal antibody, typically starting at about 3-4 weeks of age" (p. 2, lines 7-9 of the specification). Thus,

conventional wisdom is to deliver vaccine at 3-4 weeks of age, *not* during the first few days of life, as stated by the Examiner. However, as further noted by Applicants, vaccination is burdened by a number of problems, such as the difficulty of predicting exactly when the maternal antibodies have waned, requiring multiple administrations of the vaccine, which leads to further problems such as expense and stress on the birds. Applicants solution to this problem is injection of the vaccine *in ovo*, followed by sustained release of the immunogen at least until the bird is capable of mounting an immune response to the immunogen. Applicants respectfully assert that these elements of Applicants' claims are not provided by the combination of Emery et al. in view of Phelps et al. in view of Genovese et al., and further is not available as common knowledge.

Applicants further respectfully disagree that the Examiner has provided a *prima facie* case of obviousness, as the Examiner has not provided a suggestion or motivation to modify the references or to combine the teachings of Emery et al. in view of Phelps et al. in view of Genovese et al. to provide a *prima facie* case of obviousness.

The Examiner has asserted that "one of ordinary skill in the art would have been motivated to administer a sustained-release formulation *in ovo*, to a bird (i.e., poultry such as chicken) wherein the formulation comprised a siderophore receptor such as enterochelin, and wherein the sustained-release formulation was sustained until the hatching of the bird (i.e., 1-60 or 1-90 days post hatching) in order to increase the bird's immune system to foreign disease causing bacteria" (Office Action at the last paragraph of page 7). It is noted that the claims do not recite "sustained until the hatching of the bird"; they recite "for sustained release of the immunogen at least until the bird is capable of mounting an immune response to the immunogen" (independent claims 34 and 84) or "for sustained release of the immunogen until a time when maternal antibodies of the bird to the immunogen are sufficiently reduced so that the bird is capable of mounting an immune response to the immunogen" (independent claim 69). It is also noted that none of the cited references state 1-60 or 1-90 days post hatching, thus it appears that the Examiner is using information gleaned only from the applicants' disclosure. In this regard the

Examiner is respectfully reminded that "impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art" (M.P.E.P §2142).

The basis of the motivation, as stated by the Examiner, appears to the found in the statement that "[i]t was clear from the prior art that siderophore receptors from gram-negative bacterial were known to vaccinate birds, and suggested for use *in ovo* by Emery et al." (Office Action at page 8). Emery et al. states that "[t]he vaccine may be delivered to the animal, for example, by parenteral delivery, injection (subcutaneous or intramuscular), sustained-released repository, aerosolization, egg inoculation (i.e., poultry), and the like" (column 11, lines 12-16). While Emery et al. briefly suggests egg inoculation, it does not suggest, or provide a motivation, to provide sustained release as recited in claims 34, 69, or 84 of the immunogen at least until the bird is capable of mounting an immune response to the immunogen, but rather merely suggests that the vaccine may be administered to eggs. Emery et al. is also silent with regard to the role of maternal antibodies and the development of the chick's immune system, and how this might influence the timing of vaccination.

There is further no motivation in Phelps et al. to provide sustained release of the immunogen at least until the bird is capable of mounting an immune response to the immunogen, or until a time when maternal antibodies of the bird to the immunogen are sufficiently reduced so that the bird is capable of mounting an immune response to the immunogen. As noted above, Phelps et al. discloses a method of introducing a substance into a bird egg utilizing a seal to minimize ingress of air and contaminants, and minimize the leakage of albumin from the egg. While Phelps et al. does make passing reference to the delivery of vaccines as one of the many substances that may be injected by this method, Phelps contains no suggestion or motivation to provide sustained release of the immunogen at least until the bird is capable of mounting an immune response to the immunogen, and further contains no discussion of the role of maternal antibodies or the development of the chick's immune system.

There is also no further motivation in Genovese et al. to provide sustained release of the immunogen at least until the bird is capable of mounting an immune response to the immunogen,

or until a time when maternal antibodies of the bird to the immunogen are sufficiently reduced so that the bird is capable of mounting an immune response to the immunogen.

To establish a *prima facie* case of obviousness, there must also be a reasonable expectation of success. A reasonable expectation of success is highly correlated to the predictability of the field of endeavor. Applicants respectfully suggest that immunization can be a highly unpredictable art, and that this unpredictability is further increased by the complex interaction between maternal antibodies and the newborn birds' immune systems. The applicants respectfully suggest that a reasonable expectation of success did not exist prior to the applicants' disclosure, and is not provided by Emery et. al. in view of Phelps et al. in view of Genovese et al.

The Examiner's reviewing board defines one of ordinary skill in the art as one "who thinks along the line of conventional wisdom in the art and is not one who undertakes to innovate, whether by patient, and often expensive, systematic research or by extraordinary insights, it makes no difference which." Ex parte Anderson, 21 USPQ2d 1241, 1256 (B.P.A.I. 1991). For the reasons set forth above, an artisan thinking along the line of conventional wisdom would not have been motivated as the Examiner suggests, nor would an artisan of ordinary skill have had a reasonable expectation of success, absent the benefit of hindsight provided by the present specification.

For at least these reasons, reconsideration and withdrawal of the present rejection is respectfully requested.

The Examiner rejected claims 34-44 under 35 U.S.C. §103(a) as being unpatentable over Emery et al. (U.S. Patent No. 5,830,479) in view of Phelps et al. (U.S. Patent No. 5,339,766) and further in view of Evans et al. (U.S. 6,500,438 B2) in view of Genovese et al. (Avian Pathology, 1998, Vol. 27(6), pg. 597). This rejection is respectfully traversed.

The text of this rejection is essentially identical to the language used in the earlier rejection of claims 34-44 under 35 U.S.C. §103(a) as being unpatentable over Emery et al. in view of Phelps et al. and further in view of Evans et al. in the Office Action dated July 28, 2006.

The present rejection now includes the Genevese et al. document. Thus, the comments made by the applicant regarding this rejection in the response dated December 28, 2005, are respectfully maintained.

The Examiner restates an argument made by the applicant in the response dated December 28, 2005, (see the present Office Action at page 10, last paragraph), and then states that "Evans et al. support th rejection because Evans et al. teach that it was known to inject poultry at the claimed times in order to illicit an immune response regardless of what type of immunogen they were administering." First of all, this is an extreme over-generalization of the arguments made by the applicant in the response dated December 28, 2005, and the Examiner does not address any of the other arguments made in that earlier response. Secondly, the Examiner's assertion that "Evans et al. teach that it was known to inject poultry at the claimed times in order to illicit an immune response regardless of what type of immunogen they were administering" is false. Evans does not teach or suggest their method can be used for any immunogen, and the Examiner's conclusion that Evans does teach the use of any immunogen is conjecture.

The Examiner is requested to consider that, as described above, Emery et al. in view of Phelps et al. in view of Genovese et al. does not teach or suggest all the claim limitations of claims 34-44, i.e., Emery et al. in view of Phelps et al. in view of Genovese et al. does not provide "for sustained release of the immunogen at least until the bird is capable of mounting an immune response to the immunogen" (independent claim 34). This deficiency is not supplemented by the inclusion of Evans et al. Likewise, as described above there is no motivation or reasonable expectation of success.

For at least these reasons, reconsideration and withdrawal of the present rejection is respectfully requested.

Summary

It is respectfully submitted that the pending examined claims are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives, at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted
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August 24, 2006
Date

By: David L. Provence
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CERTIFICATE UNDER 37 CFR §1.8:
The undersigned hereby certifies that the Transmittal Letter and the paper(s), as described hereinabove, are being transmitted by facsimile in accordance with 37 CFR §1.6(d) to the Patent and Trademark Office, addressed to **Mail Stop Amendment**, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 24th day of August, 2006, at 3:02 p.m. (Central Time).

By: R. Cinelli-Graham
Name: Rachel Cinelli-Graham

EXHIBIT A

PATENT
Docket No. 293.00010102

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s):	Emery et al.	Group Art Unit:	1642
Serial No.:	10/749,602	Examiner:	Unassigned
Confirmation No.:	8548		
Filed:	December 31, 2003		
For:	IN OVO DELIVERY OF AN IMMUNOGEN CONTAINING IMPLANT		

REQUEST FOR CORRECTED FILING RECEIPT

Mail Stop Missing Parts
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Upon review of the Filing Receipt received from the U.S. Patent and Trademark Office in connection with the above-identified application, the following error was noted.

The first-named inventor's first name is misspelled as "Darryl." The correct spelling is Daryll. A copy of the Filing Receipt with this correction marked in red is enclosed. Applicants respectfully request a corrected Filing Receipt.

If the Examiner has any questions regarding this submission, please contact Applicants' Representative at the below-listed telephone number.

CERTIFICATE UNDER 37 C.F.R. 1.10:

The undersigned hereby certifies that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR §1.10 on the date indicated below and is addressed to the Commissioner for Patents, Mail Stop Missing Parts, P.O. Box 1450, Alexandria, VA 22313-1450

Name: Rachel Bayliardi-Graham
"Express Mail" mailing label number: EV 405460027 US
Date of Deposit: JUNE 25, 2004

June 25, 2004
Date

Respectfully submitted for

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EXHIBIT B

PSIT

DKT 1

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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Alexandria, Virginia 22313-1450
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APPL NO.	FILING OR 371 (c) DATE	ART UNIT	FIL FEE REC'D	ATTY.DOCKET NO	DRAWINGS	TOT CLMS	IND CLMS
10/749,602	12/31/2003	1642	1770	293.00010102	3	66	5

PSIT
4/29/04 Formal Dwgs
4/30/04 Pair
7/30/04 Publ?

CONFIRMATION NO. 8548

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FILING RECEIPT

OC000000012486090

Date Mailed: 04/30/2004

Receipt is acknowledged of this regular Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please write to the Office of Initial Patent Examination's Filing Receipt Corrections, facsimile number 703-746-9195. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).**

Applicant(s) Daryll
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Assignment For Published Patent Application
Willmar Poultry Company, Inc., Willmar, MN;

Domestic Priority data as claimed by applicant
This application is a DIV of 09/449,271 11/24/1999 PAT 6,682,754

Foreign Applications

If Required, Foreign Filing License Granted: 04/29/2004

Projected Publication Date: To Be Determined - pending completion of Missing Parts

Non-Publication Request: No

Early Publication Request: No

Title
In ovo delivery of an immunogen containing implant

RECEIVED
MAY 03 2004
MUETING & RAASCH